PHILIPS

Philips Medical Systems Nederland B.V.

K130278

510(k) Summary

MAY 2 9 2013

MR Permeability

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. General Information

21 CFR 807.92 (a)(1), (2)

Company Name:	Philips Medical Systems
Address:	595 Miner Rd Cleveland, Ohio 44143 USA
Contact Person:	Susan Quick
Telephone Number:	440-483-2291
Prepared (date):	2013 February 22
Manufacturing Site:	Philips Medical Systems Nederland B.V. Veenpluis 4-6 5684 PC Best The Netherlands
Trade Name of Device:	MR Permeability
Classification:	Class II
Regulatory Section:	Picture Archiving and Communication System 892.2050
ProCode:	90 LLZ

21 CFR 807.92(a)(3):Legally marketed predicate device to which substantial equivalence is claimed:

Predicate Device:	nordicICE Software
Manufacturer:	NordicNeuroLab
Predicate Device k#:	K090546

21 CFR 807.92(a)(4): Description of the device that is the subject of this premarket notification:

1. Summary of functions of the device and its major components

IntelliSpace Portal is a multimodality (CT, NM, and MR) thin-client applications server that delivers full diagnostic viewing and clinical applications to the enterprise. IntelliSpace Portal is a medical software system that allows multiple users to remotely access IntelliSpace Portal from compatible computers on a network. The system allows networking, selection, processing and filming of multimodality DICOM images. Both the client and server software are only for use with off the shelf hardware technology that meets defined minimum specifications. The device is not intended for diagnosis of lossy compressed images. For other images, trained physicians may use the images as a basis for diagnosis upon ensuring that monitor quality, ambient light conditions and image compression ratios are consistent with clinical application.

The MR Permeability integrated into the IntelliSpace portal is used for processing MR T1 images to generate parametric maps, which help in studying micro-vascular properties. It is a client-server based application developed using Philips Informatics Infrastructure (PII) platform and is integrated into IntelliSpace portal. Communication and data exchange between client-server and with other portal components use standards like TCP/IP and DICOM.

The following are major functions available in the application:

a. Selection of input T1 Dynamic Contrast Enhanced (DCE) images and reference T1 W images.
b. Automatic registration.
c. Calculation of following permeability maps using default and manual Arterial Input Function (AIF):
   - Vascular permeability (Ktrans)
   - Tracer efflux rate (Kep)
   - Extravasular volume fraction (Ve)
   - Plasma fraction (Vp)
   - Area under the curve (AUC)
d. Calculation of permeability results for Region of Interest (ROI).
e. Presentation of results in form of maps, table of results and graphs.
f. Standard image visualization including windowing, color LUT and fusion.
g. Preview and background modes of processing with saving of maps to portal database in background mode.
h. Filming and reporting by interfacing with filming and reporting applications in

portal.

21 CFR 807.92(a)(5): Intended Use

- MR Permeability facilitates the radiologist in visualizing and post-processing dynamic contrast- enhanced datasets. It is an optional package within IntelliSpace Portal.
- MR Permeability can be used by the radiologist to assess the micro-vascular properties by computing vascular permeability (Ktrans), tracer efflux rate (Kep), extravascular volume fraction (Ve), plasma fraction (Vp), and Area under the curve (AUC) from T1 images of the brain or prostate. The applied pharmacokinetic modeling is based on the Tofts model.
- The results are presented back to the user in the form of a parametric map, a table of results and in a graph.
- MR Permeability facilitates the visualization of areas with increased permeability.
- MR Permeability facilitates the visualization of variations in permeability.
- MR Permeability is a software tool for visualizing and post processing dynamic contrast-enhanced 3D datasets, acquired to visualize areas with abnormal vascularity.

21 CFR 807.92(a)(6): Technological Characteristics:

MR Permeability within the IntelliSpace portal is used for processing MR T1 images to generate parametric maps, which help in studying micro-vascular properties. It is a client-server based application developed using Philips Informatics Infrastructure (PII) platform and is integrated into IntelliSpace portal.

Client part of the application runs on portal client, which is a PC running standard Microsoft Windows Operating System. Typical hardware for client might include:

- PC with specified operating system, system memory, monitor, keyboard and mouse.
- Hard Disk for client software.
- Network port to connect to the network.

Server part of the application runs on portal server, which is server class hardware running standard Microsoft Windows Operating System. Typical hardware for server might include:

- Server class hardware with specified operating system, system memory, monitor, keyboard and mouse.
- Hard Disk for server software and data storage.
- Network port to connect to the network.
- CD/DVD ROM drive for software installation.

The second Portal Servers (Slave server) can be used in a master-slave scenario enabling the additional processing capacity (more users in the same time) if needed. There is only one database of studies shared between slaves and master.

The Permeability Package within IntelliSpace Portal, provided by Philips Healthcare, enables assessing variations in permeability in various tissues. The required input is a dynamic T1-weighted image series that enables analysis and visualization of variations in contrast leakage. nordicICE Perfusion/DCE Module

of the nordicICE Software from NordicNeuroLabs provides the same analysis and visualization, based on the same image input.
- Both packages visualize and analyze or process dynamic data and changes in contrast over time. They both use permeability or leakage as the key focus of the intended use.
- The nordicICE is a complete off-the-shelf PC workstation, while MR Permeability is one of the processing capabilities of our IntelliSpace Portal workstation solution. This does not affect the functionality of the software.

The MR Permeability Software Application is similar to the predicate device, nordicICE Perfusion/DCE Module which has been cleared through premarket notification and raises no new issues of safety or effectiveness.

Tabular comparison of features and specifications of MR Permeability and the predicate device nordicICE Software.

	Philips Healthcare MR Permeability	**NordicImagingLab nordicICE Software (K090546)**
DICOM	Yes	Yes
Intended Use	MR Permeability package facilitates the radiologist in visualizing and post-processing dynamic contrast-enhanced datasets. It is an optional package within IntelliSpace Portal. MR Permeability Package can be used by the radiologist to assess the micro-vascular properties by computing vascular permeability (Ktrans), tracer efflux rate (Kep), extravascular volume fraction (Ve), plasma fraction (Vp), and Area under the curve (AUC) from T1 images of the brain or prostate. The applied pharmacokinetic modeling is based on the Tofts model. The results are presented back to the user in the form of a parametric map, a table or results in a graph. MR Permeability Package facilitates the visualization of areas with increased permeability. MR Permeability Package is a software tool for visualizing and post-processing dynamic contrast-enhanced 3D datasets, acquired to visualize areas with abnormal vascularity.	Nordic Image Control and Evaluation (nordicICE) software is an image processing software package to be used by trained professionals including but not limited to physician and medical technicians. The software runs on a standard "Off-the-shelf" PC workstation and can be used to perform image viewing, processing and analysis or medical images. Data are images acquired through DICOM complaint imaging devices and modalities. nordicICE provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including blood oxygen level dependent (BOLD) fMRI, diffusion weighted MRI (DWI), Fiber Tracking and dynamic analysis. **BOLD fMRI:** BOLD analysis is used to highlight small magnetic susceptibility changes in the human brain in areas with altered blood-flow resulting from neuronal activity. **DWI/Fiber Tracking**: Diffusion analysis is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. Fiber tracking utilize the directional dependency of the diffusion to display the white matter structure in the brain. **Dynamic Analysis:** Dynamic analysis is used for visualization and analysis of dynamic imaging data of the brain, showing properties of changes in contrast over time where such techniques are useful or necessary. nordicICE Perfusion Module: Calculation of parameters related to tissue flow (perfusion) and tissue blood volume nordicICE DCE Module: calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space.
Generate Various Parametric Maps:	Yes	Yes
• KTrans	Yes	Yes
• V	Yes	Yes
• AUC	Yes	Yes
• KEP	Yes	Yes

	Philips Healthcare MR Permeability	NordicImagingLab nordicICE Software
• Plasma Fraction	Yes	Yes
Detailed analysis based on user defined ROI's	Yes	Yes
Input based on Dynamic T1-weighted measurements	Yes	Yes
Underlay selection	Yes	Yes
Calculation based on Tofts Model	Yes	Yes
Applicable to multiple organs and tissues	Yes – Brain and Prostate	Yes
Graph presentation of data	Yes	Yes

21 CFR 807.92(b)(1): Brief discussion of nonclinical tests submitted, referenced or relied on in this premarket notification:

The MR Permeability verification tests were performed on the complete system relative to the verification, regression and test specifications. Corresponding test results are included in this submission and for each specification indicate verification purpose was accomplished.

21 CFR 807.92(b)(2): Brief discussion of clinical tests submitted, referenced or relied on in this premarket notification:

The conclusion from testing the device against synthetic data as well clinical data is: "Based on the test results, the MR Permeability analysis functions according to its intended use".
All defects have been analyzed and it are confirmed that they are not safety defects and will not cause any hazardous situation on using this application.

21 CFR 807.92(b)(3): The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section:

The nonclinical and clinical tests have demonstrated that the device is safe and works according to its intended use.

The MR Permeability software does not introduce new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems considers MR Permeability to be substantially equivalent to the NordicNeuroLab – nordiciCE Software (K090546).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 29, 2013

Philips Medical Systems Nederland B.V.
% Ms. Susan Quick
Regulatory Affairs Specialist
Philips Medical Systems (Cleveland), Inc.
595 Miner Road
CLEVELAND OH 44143

Re: K130278
Trade/Device Name: MR Permeability
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 6, 2013
Received: March 7, 2013

Dear Ms. Quick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

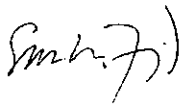
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130278

Device Name: MR Permeability

Indications for Use:

- MR Permeability facilitates the radiologist in visualizing and post-processing dynamic contrast-enhanced datasets. It is an optional package within IntelliSpace Portal.
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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130278